REMARKS/ARGUMENTS

Claims 7 and 9-13 are pending in this application. Claims 1-6, 14- 30 were previously canceled. Claim 8 is canceled herein without prejudice. Applicants reserve the right to file one or more continuation, continuation-in-part, or divisional applications towards any withdrawn or canceled subject matter. Claims 7, 9, and 10 are amended herein. Basis for these amendments may be found throughout the specification and claims as originally filed. For example, basis for the amendments in claim 7 may be found in claim 8 as originally filed. Other claim amendments provide the correct claim dependencies. No new matter has been added.

Claim Rejections - 35 U.S.C. §102

Claims 7-13 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Badorff et al. (Nature Medicine, Vol. 5: 320-326, 1999). Applicants respectfully traverse the rejection as it might apply to the pending claims.

To anticipate a claim, the cited reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). It is respectfully submitted that as amended herein, the instant claims are not anticipated by Badorff.

The invention as defined by the claims, distinguishes over Badorff by claiming a method for detecting an enteroviral infection in a subject's heart by in vitro immunological detection of a dystrophin cleavage product in blood or cardiovascular tissue obtained from the subject, wherein the dystrophin cleavage product is produced by enteroviral protease 2A cleavage of the rod domain of dystrophin, wherein the detection is performed in an immunoassay using a detectably labeled dystrophin epitope-specific antibody or Fab fragment thereof, which is specific to the dystrophin cleavage product produced by enteroviral protease 2A cleavage of the rod domain of dystrophin, and wherein binding of the antibody indicates that a dystrophin cleavage product resulting from an enteroviral infection is present in the blood or cardiovascular tissue assayed.

As discussed in the specification, the claimed method provides for a highly sensitive and specific diagnostic procedure for determining whether a patient's heart is infected with an enterovirus. This method can be applied either in vitro or in vivo through a simple blood test or through myocardial imaging. By contrast, the existing methods for diagnosing myocardial viral infections require that heart tissue be biopsied for laboratory analysis and, even then, the test is of "limited sensitivity and specificity" (see, Feldman and McNamara, New Engl. J Med., 343:1388-1398, at 1393 (2000)). Thus, the claimed methods provide a significant improvement in diagnostic techniques for virus mediated acquired cardiomyopathy.

Badorff does not disclose any such methods. Instead, this reference discloses that the enteroviral protease 2A cleaves dystrophin at the predicted residue sites and consequently, leads to dilated cardiomyopathy and heart failure. In particular, this reference discloses incubating protein extracts from cultured rat neonatal ventricular myocytes with purified recombinant Coxsackieviral protease 2A, in which the protein extracts were analyzed by western blot analysis using the Dy4/6D3 antibody, to confirm the predicted cleavage sites at the 588 and 2,434 residues in humans. This reference also discloses that the Dy4/6D3 antibody recognizes the rod domain of dystrophin (see, Figure 1 on page 321 for the region of dystrophin used to generate the Dy4/6D3 antibody). This antibody however, does not recognize the specific dystrophin cleavage products produced, for example, the 588 and 2,434 residues, in order to detect an enteroviral infection as required by the instant claims. In fact, the Dy4/6D3 antibody recognizes intact dystrophin, as well as any fragments of this protein that includes the rod domain.

By contrast, the instant claims are directed to methods for detecting an enteroviral infection by detecting the dystrophin cleavage products using a detectably labeled dystrophin epitope-specific antibody or Fab fragment thereof, which is specific for the dystrophin cleavage product produced by the enteroviral protease 2A cleavage of the rod domain of dystrophin, i.e. the 588 and 2,434 cleavage products. Thus, the claimed methods directly detect the enteroviral cleavage products in blood or cardiovascular tissue for detecting an enteroviral infection, whereas Badorff discloses using the Dy4/6D3 antibody to detect fragments of dystrophin (that have the required rod domain) after exposure to Coxsackieviral protease 2A for identifying the predicted

cleavage sites (at residues 588 and 2,434). As such, Applicants respectfully submit that the claims 7 and 9-13 are not anticipated by the disclosure of Badorff. Applicants request reconsideration and removal of this rejection.

CONCLUSION

Applicants submit that pending claims 7 and 9-13 are in condition for allowance. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this submission.

No fee is believed to be due in connection with this submission. However, the Commissioner is hereby authorized to charge any other fees associated with the filing submitted herewith, or credit any overpayments to Deposit Account No. 07-1896 referencing the above-identified attorney docket number.

Respectfully submitted,

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